The Department of Health and Human Services Meeting of the

Secretary's Advisory Committee on Human Research Protections (SACHRP) Tuesday, October 9, 2012 – Wednesday, October 10, 2012 Hubert H. Humphrey Building, Room 705A **AGENDA**

Tuesday, October 9, 2012

8:30 am – 8:45 am	Welcome: Opening Remarks Barbara Bierer, M.D. SACHRP Chair
	Jerry Menikoff, M.D., J.D. Director, OHRP
8:45 am- 9:15 am	Opening Remarks, Swearing in of New Member Howard K. Koh, M.D., M.P.H. Assistant Secretary for Health
9:15 am- 10:15	Subpart A Subcommittee (SAS) Daniel K. Nelson, M.S., CIP, SAS Co-chair David Borasky, M.P.H., CIP, SAS Co-chair
10:15 am – 10:30 am	BREAK
10:30 am – 12:00 pm	SAS Discussion
12:00 pm – 1:00 pm	LUNCH
1:00 pm – 1:30 pm	Legal Status of E-Signatures Laura Odwazny, J.D.

1:30 pm - 3:30 pm**Informed Consent Issues in Cluster Randomized Trials**

Public Health Division Office of General Counsel

Senior Attorney

Andrew McRae, MD, Ph.D. University of Calgary

Public Comment 3:30 pm - 3:45 pm

3:45 pm - 4:00 pmWrap-up Discussion and Adjourn

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Wednesday, October 10, 2012

8:30 am – 8:45 am **Opening Remarks**

Barbara Bierer, M.D. SACHRP Chair

Jerry Menikoff, M.D., J.D.,

Director, OHRP

8:45 am- 10:30 am Subcommittee on Harmonization (SOH)

David Forster, J.D., SOH Co-chair Mark Barnes, J.D., SOH Co-chair

10:30 am – 10:45 pm BREAK

10:45 am- 12:30 pm NeuroNext IRB Experience

Pearl O'Rourke, M.D.

Director of Human Research Affairs for Partners

HealthCare

Louise Ritz, M.B.A.

NIH/NINDS/Office of Clinical Research Clinical Research Program Manager

12:30 pm- 1:30 pm LUNCH

1:30 pm – 3:30 pm Internet Research

Elizabeth Buchanan, Ph.D. Endowed Chair in Ethics

Director of the Center for Applied Ethics

University of Wisconsin-Stout

Dean R. Gallant, A.B.

Assistant Dean for Research Policy and Administration Harvard University

3:30 pm – 3:45 pm **Public Comment**

3:45 pm – 4:00 pm Wrap-up Discussion and Adjourn